

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Shinichiro Morita et al.  
App. No : 10/070,938  
Filed : June 4, 2002  
For : MATRIX FOR REGENERATING  
CARDIOVASCULAR TISSUE AND  
METHOD FOR REGENERATING  
CARDIOVASCULAR TISSUE  
Examiner : David M. Naff  
Art Unit : 1657  
Conf No. : 4758

REQUEST FOR REHEARING OF BOARD OF PATENT APPEALS AND INTERFERENCES  
DECISION UNDER 37 C.F.R. § 41.52

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Decision on Appeal by the Board of Patent Appeals and Interferences, decided June 4, 2009 and mailed from the United States Patent and Trademark Office on June 8, 2009, Applicants request that the Board reconsider the decision on the basis of the following remarks.

**Discovering a Source/Cause of a Problem is Part of an Invention**

The Board erred by failing to give proper weight to the Applicants' discovery of the source of a problem as part of an "as a whole" inquiry. Referring to MPEP 2141.02, the discovery of the source of a problem is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103." Citing *In re Sponnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969).

At page 14, first full paragraph, of the Decision on Appeal, the Board referred to "Appellants arguments that they have discovered an unknown problem." This is actually not the

basis of Appellants' argument. Rather, the Appellants have discovered the source of a known problem. Specifically, it was known that engineered cardiovascular grafts of tissue grown on fiber-based materials, are subject to catastrophic failure, even if the tissue growth is apparently complete before implantation. There could be any number of sources for such catastrophic failure. As just some examples for possible sources of the problem, the tissue itself could be degraded by bodily processes, the fibers could be incompatible with the environment in which they are placed, the blood flowing through the cardiovascular tissue could create an undesirable flow around the valve, or the cardiovascular tissue could overgrow the graft.

The Applicants discovered that the source of the problem was a lack of structural integrity in unreinforced fibers. As set forth in the M.P.E.P., this discovery must be considered as part of the invention a whole when evaluating the patentability of the present subject matter. The solution to the problem was reinforcing the material with a separate biodegradable reinforcement prior to seeding cells onto the material. The Decision on Appeal determined that this solution would have been obvious to one having ordinary skill in the art. However, the Decision did not consider that part of the invention included the discovery of the source of the problem to which the solution is addressed. As set forth in the M.P.E.P., "a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified." Thus, the Board's decision that the remedy to the problem, namely the incorporation of the reinforcements, was obvious did not entirely address the patentability of Appellants' invention "as a whole."

The present application is analogous to *In re Sponnoble*, where the discovery of the source of a problem was found to be part of the invention. In *In re Sponnoble*, the claim was directed to a plural compartment mixing vial wherein a center seal plug was placed between two compartments for temporarily isolating a liquid-containing compartment from a solids-containing compartment. The claim differed from the prior art in the selection of butyl rubber with a silicone coating as the plug material instead of natural rubber. The prior art recognized that leakage from the liquid to the solids compartment was a problem, and considered the problem to be a result of moisture passing around the center plug because of microscopic fissures inherently present in molded or blown glass. The court found the inventor discovered the cause of moisture transmission was through the center plug, and there was no teaching in the prior art which would

suggest the necessity of selecting applicant's plug material, which was more impervious to liquids than the natural rubber plug of the prior art.

In the present case, Claims 7-9, 11 and 15-19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vacanti, et al., United States Patent No. 5,855,610, in view of Vyakarnam, et al., United States Patent No. 6,534,084 and Morita, Japanese Patent No. 3-23864. Vacanti et al. discloses "reconstruction and augmentation of flexible, strong connective tissue such as arteries and heart valves." Vacanti et al. recognized that, in some embodiments, it may be desirable to include "struts." The struts are described as imparting "resistance to mechanical forces," thereby yield[ing] the desired shape. Vacanti at col. 3, lines 65-66. However, Vacanti et al. did not recognize the source of the problem discovered by Appellants. Rather, Vacanti et al. indicated that the struts were for "push[ing] the surrounding tissue and skin up and away from the implanted cells." Thus, Vacanti believed the source of the problem to be the surrounding tissue and skin coming into contact with the surrounding cells. Appellants specifically rejected this as the source of the problem by placing their reinforcements "integrated with the sponge and located inside or on the exterior surface of the matrix." This recited structure places at least some of the cells in a position that would be forced against the surrounding tissue by action of the internal struts. Thus, Appellants' recited structure implicitly rejects Vacanti's view of the source of the problem.

Nothing in Vacanti or any of the other cited references described that the catastrophic failure that often occurs when implanting cardiovascular grafts results from insufficient structural integrity of the sponge. As discussed above, such catastrophic failure could have resulted from any of numerous different sources. It was only through Appellants' discovery that the source was identified as insufficient structural integrity.

In contrast to the combination of cited references, the Appellants have identified the source of the problem that, engineered cardiovascular grafts of tissue grown on unreinforced fiber-based materials, are subject to catastrophic failure, even if the tissue growth is apparently complete before implantation. Applicants discovered that the source of this problem was structural failure of the matrix. Based on this discovery, Applicants developed the solution of seeding cells on a matrix comprising a sponge configured to regenerate cardiovascular tissue and made of a bioabsorbable material and a reinforcement made of a bioabsorbable material, the reinforcement being integrated with the sponge and located inside or on the exterior surface of the

matrix. Without an appreciation of the source of the problem of catastrophic failure by unreinforced fiber based materials, there was no reason for one of skill in the art to develop the presently claimed methods. Even if one of ordinary skill in the art was aware of the problem of catastrophic failure by tissue grafts grown on unreinforced fiber-based materials, such a problem could result from any number of different sources. Once Appellants discovered the specific source of the problem, even if the solution to this problem is obvious, the invention as a whole is still patentable.

Similar to the conclusion reached in *In re Spomnoble*, there is no teaching in the prior art which would suggest the necessity for cardiovascular tissue grafts having “a reinforcement made of a bioabsorbable material, the reinforcement being integrated with the sponge and located inside or on the exterior surface of the matrix,” as recited in Claim 7. Because such a limitation could only be obvious in view of Appellants’ discovery of the source of the problem solved by this feature, reversal of the rejections under § 103 is believed appropriate.

### **Claims 7-11 and 15-19 Are Not Indefinite Under 35 U.S.C. § 112**

Although the Board affirmed the Examiner’s rejections, the Board did not specifically address the rejection under 35 U.S.C. § 112. As set forth in Appellants’ brief, the Examiner alleged that the meaning of “reinforcement being integrated with the sponge” to be “uncertain as to meaning and scope,” because “the specification fails to define the difference between being integrated and not integrated with the sponge.” Examiner’s Office Action at 2. In effect, the Examiner had penalized Appellants for choosing to rely on the ordinary meaning of “integrated” rather than act as their own lexicographers. Surely there is no need for the Appellants to separately define such a well-understood term. Webster’s, for example, defines the word as “combining or coordinating separate elements so as to provide a harmonious, interrelated whole.” Webster’s Encyclopedic Unabridged Dictionary of the English Language 738. An example thereof is shown in Figure 1 of the present application, which depicts the reinforced matrix prior to the seeding of cells thereon. Vacanti’s struts, in contrast, which may be implanted before the seeded matrix, are clearly separate from the cell matrix and thus cannot be “integrated” with it. The “reinforcement being integrated with the sponge” limitation is not indefinite and the rejection of the pending claims under 35 U.S.C. § 112 should be reversed.

### CONCLUSION

In view of the foregoing, the Applicants respectfully submit that the pending claims are not obvious in view of the cited prior art combination. The Applicants respectfully request that rejection under 35 U.S.C. § 103(a) be reversed, that the rejection under 35 U.S.C. § 112 with regard to indefiniteness be reversed, and that the application be allowed.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 4, 2009

By: \_\_\_\_\_ /daniel altman/  
Daniel E. Altman  
Registration No. 34,115  
Attorney of Record  
Customer No. 20995  
(949) 760-0404

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